

IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF
PENNSYLVANIA

UNITED STATES OF AMERICA,)	Civil Action No. 2:11-cv-01498-AJS
Plaintiff,)	United States Judge Arthur J. Schwab
v.)	<i>Electronically Filed</i>
ATF FITNESS PRODUCTS, INC.,)	
and MANUFACTURING ATF)	
DEDICATED EXCELLENCE, INC.)	
corporations, and JAMES G. VERCELLOTTI,)	
an individual))	
Defendants.)	

JURY TRIAL DEMANDED

ANSWER AND AFFIRMATIVE DEFENSES TO COMPLAINT FOR INJUNCTION

AND NOW, come Defendants ATF Fitness Products, Inc. (“ATF”), Manufacturing ATF Dedicated Excellence, Inc. (“MADE”), and James G. Vercellotti (“Vercellotti”) (collectively “Defendants”), by and through their attorneys, Joseph A. DiMenno, Esquire, Dickie, McCamey & Chilcote, P.C., Michael J. DiMaggio, Esquire, and Collins, McDonald & Gann, P.C., and file this Answer and Affirmative Defenses to Complaint for Injunction, averring as follows:

1. Defendants state that the allegations set forth in paragraph 1 and subparagraphs (a) through (c) of the Complaint contain legal conclusions to which no response is required. To the extent a response is required, said allegations are denied.

2. Defendants state that the allegations set forth in paragraph 2 of the Complaint contain legal conclusions to which no response is required. To the extent a response is required, said allegations are denied.

3. Defendants state that the allegations set forth in paragraph 3 of the Complaint contain legal conclusions to which no response is required. To the extent a response is required, said allegations are denied.

4. Admitted.

5. Admitted.

6. Admitted in part and denied in part. It is admitted that Vercellotti is an individual with ownership interests in, and management responsibilities in connection with, ATF and MADE. All remaining allegations set forth in paragraph 6 of the Complaint are denied as stated.

7. Defendants state that the allegations set forth in paragraph 7 of the Complaint contain legal conclusions to which no response is required. To the extent a response is required, said allegations are denied.

8. Denied as stated. It is admitted that MADE manufactures dietary supplements and ATF distributes dietary supplements. All remaining allegations and any allegations to the contrary are denied.

9. Admitted in part and denied in part. It is admitted that the United States Food and Drug Administration (“FDA”) inspected Defendants’ facility on or about the time period from March 15, 2011 through April 12, 2011. Defendants state that the remaining allegations set forth in paragraph 9 of the Complaint contain legal conclusions to which no response is required. To the extent the remaining allegations set forth in paragraph 9 of the Complaint allege facts, after reasonable investigation Defendants are without knowledge or information sufficient to form a belief as to the veracity of the same. Therefore, said allegations are denied as stated. By way of

further response, any and all inspections instituted by the FDA, and apparent results of such inspections, lie clearly within the knowledge of Plaintiff United States of America ("Plaintiff"). Finally, any such inspections and results speak for themselves, to the extent the FDA documented the same.

10. Defendants state that the allegations set forth in paragraph 10 of the Complaint contain legal conclusions to which no response is required. To the extent a response is required, said allegations are denied.

11. It is specifically admitted that FDA inspected Defendants' facility on or about the time period from March 15, 2011 through April 12, 2011. To extent the remaining allegations of Paragraph 11 allege facts, after reasonable investigation Defendants are without knowledge or information sufficient to form a belief as to the veracity of the same. Therefore, said allegations are denied as stated. By way of further response, any and all inspections instituted by the FDA, and apparent results of such inspections, lie clearly within the knowledge of Plaintiff. Finally, any such inspections and results speak for themselves, to the extent the FDA documented the same.

11(a) – (j). Defendants state that the allegations set forth in paragraph 11, subparagraphs (a) through (j) of the Complaint contain legal conclusions to which no response is required. To the extent a response is required, said allegations are denied.

12. Defendants state that the allegations set forth in paragraph 12 of the Complaint contain legal conclusions to which no response is required. To the extent a response is required, said allegations are denied. By way of further response, any and all inspections instituted by the FDA, and apparent results of such inspections, lie clearly within the knowledge of Plaintiff.

Finally, any such inspections and results speak for themselves, to the extent the FDA documented the same.

13. Defendants state that the allegations set forth in paragraph 13 of the Complaint contain legal conclusions to which no response is required. To the extent a response is required, said allegations are denied.

14. Defendants state that the allegations set forth in paragraph 14 of the Complaint contain legal conclusions to which no response is required. To the extent a response is required, said allegations are denied.

15. After reasonable investigation, Defendants are without knowledge or information sufficient to form a belief as to the veracity of the allegations set forth in paragraph 15 and subparagraphs (a) through (c) of the Complaint. Consequently, said allegations are denied. By way of further response, any and all inspections instituted by the FDA, and apparent results of such inspections, lie clearly within the knowledge of Plaintiff. Finally, any such inspections and results speak for themselves, to the extent the FDA documented the same.

16. Defendants state that the allegations set forth in paragraph 16 of the Complaint contain legal conclusions to which no response is required. To the extent a response is required, said allegations are denied.

17. Defendants state that the allegations set forth in paragraph 17 of the Complaint contain legal conclusions to which no response is required. To the extent a response is required, said allegations are denied.

18. Defendants state that the allegations set forth in paragraph 18 of the Complaint

contain legal conclusions to which no response is required. To the extent a response is required, said allegations are denied.

19. Defendants state that the allegations set forth in paragraph 19 of the Complaint contain legal conclusions to which no response is required. To the extent a response is required, said allegations are denied.

20. Defendants state that the allegations set forth in paragraph 20 of the Complaint contain legal conclusions to which no response is required. To the extent a response is required, said allegations are denied.

21. After reasonable investigation Defendants are without knowledge or information sufficient to form a belief as to the veracity of the allegations set forth in paragraph 21 of the Complaint. Consequently, said allegations are denied. By way of further response, any and all inspections instituted by the FDA, and apparent results of such inspections, lie clearly within the knowledge of Plaintiff. Finally, any such inspections and results speak for themselves, to the extent the FDA documented the same.

22. Defendants state that the allegations set forth in paragraph 22 of the Complaint contain legal conclusions to which no response is required. To the extent a response is required, said allegations are denied.

23. Admitted in part and denied in part. It is admitted that persons affiliated with the FDA inspection presented cursory information to Vercellotti with regard to preliminary observations apparently made. It is specifically denied that Defendants failed to respond to such preliminary observations as presented. Further, to the extent the remaining allegations set forth

in paragraph 23 of the Complaint allege facts not addressed above, after reasonable investigation Defendants are without knowledge or information sufficient to form a belief as to the veracity of the same. Therefore, such allegations are denied as stated. By way of further response, any and all inspections instituted by the FDA, and apparent results of such inspections, lie clearly within the knowledge of Plaintiff. Finally, any such inspections and results speak for themselves, to the extent the FDA documented the same.

24. Admitted in part and denied in part. It is admitted that Defendants are aware of an audit report previously prepared by an outside consultant. However, Defendants specifically deny having knowledge or information concerning any connection between the outside consultant's previously prepared audit report and any "deviations" apparently alleged by the FDA. Further, to the extent the remaining allegations set forth in paragraph 24 of the Complaint allege facts not addressed above, after reasonable investigation Defendants are without knowledge or information sufficient to form a belief as to the veracity of the same. Therefore, such allegations are denied as stated. By way of further response, any and all inspections instituted by the FDA, and apparent results of such inspections, lie clearly within the knowledge of Plaintiff. Finally, any such inspections and results speak for themselves, to the extent the FDA documented the same.

25. Defendants state that the allegations set forth in paragraph 25 and subparagraphs (a) through (c) of the Complaint contain legal conclusions to which no response is required. To the extent a response is required, said allegations are denied.

26. Defendants state that the allegations set forth in paragraph 26 of the Complaint contain legal conclusions to which no response is required. To the extent a response is required,

said allegations are denied.

WHEREFORE, Defendants ATF Fitness Products, Inc., Manufacturing ATF Dedicated Excellence, Inc., and James G. Vercellotti respectfully request for this Honorable Court to dismiss the Complaint for Injunction of Plaintiff United States of America with prejudice, to order Plaintiff United States of America to pay for all costs and attorney's fees borne by all parties in this action, and to grant such other and further relief as this Court may deem just and proper.

Any and all allegations not admitted specifically are denied.

JURY DEMAND

Defendants hereby demand a trial by a jury of twelve.

AFFIRMATIVE DEFENSES

Defendants, by their counsel, reserve the right to rely upon the following affirmative defenses to the claims asserted in the Complaint to the extent supported by evidence later developed or facts later learned, without now assuming the burden of proof on any such defense that would otherwise rest on Plaintiff and with the reservation of their rights to amend or supplement their responses to the Complaint, as well as their affirmative defenses, as information is gathered through discovery or at the time of trial:

First Affirmative Defense

Plaintiff's cause of action fails in whole or part to state a claim upon which relief can be granted.

Second Affirmative Defense

Plaintiff's cause of action is preempted by applicable state or federal law.

Third Affirmative Defense

Plaintiff's claims are barred by the applicable statute of limitations governing such claims.

Fourth Affirmative Defense

The statutory violations Plaintiff alleges were caused by events, conditions, instrumentalities, and/or acts or omissions of another individual or entity over whom or which Defendants exercised no control.

Fifth Affirmative Defense

At all material times, Defendants acted with due care and complied with applicable statutory, regulatory, and common law requirements. Accordingly, some or all of Plaintiff's claims are or may be barred by Defendants' compliance with all applicable state, federal, and local laws and regulations.

Sixth Affirmative Defense

Plaintiff is estopped to pursue relief in this action against Defendants to the extent that it proceeds with prosecution of any other action(s) in any jurisdiction against Defendants, including but not limited to those certain actions instituted prior or subsequent to this action.

Seventh Affirmative Defense

The facts Plaintiff alleged in the Complaint do not establish a sufficient legal basis for injunctive relief.

Eighth Affirmative Defense

To the extent justified by the facts developed in discovery or at the time of trial, Plaintiff's claims are barred by the doctrine of waiver.

Ninth Affirmative Defense

To the extent justified by the facts developed in discovery or at the time of trial, Plaintiff's claims are barred by the doctrine of estoppel.

Tenth Affirmative Defense

Defendants reserve the right to raise any additional defenses that they may have or as may be revealed by discovery or investigation in this matter.

WHEREFORE, Defendants ATF Fitness Products, Inc., Manufacturing ATF Dedicated Excellence, Inc., and James G. Vercellotti respectfully request for this Honorable Court to dismiss the Complaint for Injunction of Plaintiff United States of America with prejudice, to order Plaintiff United States of America to pay for all costs and attorney's fees borne by all parties in this action, and to grant such other and further relief as this Court may deem just and proper.

Respectfully submitted,

/s/ Joseph A. DiMenno

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Date: January 31, 2012